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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/813,776 03/07/97 CAVALIERE VESELY R 7063-001-0

HM22/0804
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EXAMINER

MINNIFIELD, N

ART UNIT

PAPER NUMBER

1645

10

DATE MAILED: 08/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/813,776

Applicant(s)
VESELY ET AL

Examiner
N. M. Minnifield

Group Art Unit
1645



☒ Responsive to communication(s) filed on 4/26/99 and 5/7/99

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 37-44 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 37-44 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Response to Amendment

1. Applicants' amendments filed April 26, 1999 and May 7, 1999 are acknowledged and have been entered. Claims 1-36 have been canceled. New claims 37-44 have been added and are now pending in the present application. All rejections have been withdrawn, in view of Applicants' amendments, with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file; all papers filed March 7, 1997.
4. All deposit information (Exhibits A-I and Authorization) regarding biological material is sufficient to overcome 112, first paragraph rejection as previously set forth.

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5. Claim 37 is rejected under 35 U.S.C. 102(b, d, or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saito et al (5516684 or EP 0671468) in light of Salvioli et al.

It is noted that Saito et al (5516684) is rejected under 102(e) and Saito et al (EP 0671468) is rejected under 102(b or d).

Saito et al (5516684), for example, disclose a gram positive bacterial strain which does not exhibit deconjugation of bile acids (abstract). Saito et al also disclose bacteria that "...exhibits lowering of cholesterol in blood without exhibiting deconjugation of bile acids, thereby not forming secondary bile acids..." (col. 2, l. 46-50). The bacteria do not produce the secondary bile acids since the bacteria do not exhibit deconjugation of bile acids (col. 5); therefore there is no dehydroxylase activity.

With regard to the dehydroxylase activity, it is noted that Salvioli et al disclose that "[U]nder normal conditions the deconjugation of bile acids occurs in the large bowel and perhaps in the terminal ileum; unconjugated bile acids entering the large bowel are 7'-dehydroxylated by anaerobic bacteria to yield secondary bile acids." (p. 80, col. 1). The secondary bile acids are dehydroxylated by dehydroxylase.

The claimed invention is anticipated by the prior art of Saito et al. The prior art, Saito et al, anticipates the claimed invention by disclosing the bacterial strains with the same or similar characteristics as claimed. The bacterial strains in the prior art are believed to inherently possess properties which anticipates

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the claimed invention or if they are not the same the bacterial strains of Saito et al, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the bacterial strains of the prior art are evidenced to meet the limitations of the claimed bacterial strains, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' bacterial strains with the bacterial strains of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the bacterial strains of the prior art does not possess the same material structural and functional characteristics of the claimed bacterial strains) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Determination of characteristics which vary depending on the method of analysis, such as enzymatic activity, must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent.

This rejection is maintained for the reasons of record. Applicant's arguments filed April 26, 1999 have been fully considered but they are not persuasive. Applicants have asserted that "...dehydroxylation may occur without deconjugation". The reference states that it may occur, not that it definitely does not occur.

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6. No claims are allowed.
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

August 2, 1999


NITA MINNIFIELD
PRIMARY EXAMINER